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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,284	01/29/2001	Samuel Nochumson	260/243	2969

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EXAMINER

OWENS JR, HOWARD V

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/774,284

Applicant(s)

NOCHUMSON ET AL.

Examiner

Howard V Owens

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-114 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 53-114 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim Objections

Claim 87 is objected to for the absence of a period.

In claim 93, the term "degrees" should be substituted for "degree".

Correction is required for this and any other spelling errors not noted herein.

Claim Rejections 35 U.S.C. 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 95 and 96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 95 recites the limitation "device" in claim 51. There is insufficient antecedent basis for this limitation in the claim. Accordingly, dependent claim 96 is rejected as it fails to obviate the rejection set forth in the parent claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 53, 54, 57, 64, 65, 68, 74 – 77, 91, 97-99, 101 and 104 are rejected under 35 U.S.C. § 102(b) as being anticipated by Wan et al., U.S. Patent No. 5,837,529.

Claim 53 is drawn to a method for purifying plasmid DNA, the method comprising the steps of:

(a) lysing cells containing the plasmid DNA, wherein said lysing step comprises: moving a suspension of the cells through a first passageway; moving a lysis solution through a second passageway; contacting the suspension of the cells with the lysis solution at an intersection, wherein the intersection is formed by the first and second passageway; and mixing the suspension of the cells and the lysis solution inside a third passageway to form a lysate, wherein the third passageway is downstream from the intersection;

(b) removing contaminants from the lysate, wherein the removing step comprises: moving the lysate through the third passageway and into a container, wherein the container contains a salt solution', and mixing the lysate in the salt solution to form a precipitate and a supernatant; wherein the precipitate contains the contaminants;

(c) separating the precipitate from the supernatant and (d) recovering the plasmid DNA from the supernatant.

Dependent claims 54, 57, 64 – 66, 68, 74, 75 and 77 are drawn to use of the following in accordance with claim 53, an in line mixer, 100-200 L of volume capacity, flow rate of 1 L/min., use of a non acidic unbuffered salt solution in the form of acetate or chloride, basic lysis solution, precipitate comprising contaminants consisting of RNA, chromosomal DNA, lipids and protein.

Claim 91 is drawn to a device for purifying plasmid DNA from cells containing said plasmid DNA, the device comprising: a first in-line mixer for resuspending the cells into a homogenous cell suspension. a second in-line mixer in fluid connection with the first in-line mixer for mixing the homogenous cell suspension with a lysis solution to form a lysate; a container for holding a salt solution, wherein the holding tank comprises: a mixer for mixing a salt solution in the holding tank with the lysate flowing from the second in-line mixer to form a precipitate and a supernatant; and a container outlet from which the precipitate and supernatant are removed from the tank; and at least one pump for causing the cells to flow through the first in-line mixer and the homogeneous cell suspension and lysis solution to flow through the second in-line mixer.

Dependent claims 97 – 99 and 101 are drawn to modifications of the device in accordance with claim 91 comprising a second in line mixer, a static mixer and an outlet filter for the precipitate.

Wan anticipates the claims as it teaches a method for lysing cells using a dual line feed of cell suspension and lysing solution to a primary static mixer; wherein the lysate is fed to a secondary static mixer with a precipitating solution fed separately to the secondary static mixer. Wan anticipates the dependent claims as it further teaches a flow rate of 1 L/min. (col.4, line 18), use of a non acidic unbuffered salt solution in the form of acetate or chloride (col.3, line 50), basic lysis solution (col. 3, lines 19-21),

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wherein the precipitate comprising contaminants consisting of RNA, chromosomal DNA, lipids and protein, col. 3- col.4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 53 – 114 are rejected under 35 U.S.C. § 103 as being unpatentable over Wan et al., U.S. Patent No. 5,837, 529 in combination with Kasai, J. of Chromatography, Vol. 618, pp. 203-21, 1993.

Claim 53 is drawn to a method for purifying plasmid DNA, the method comprising the steps of:

(a) lysing cells containing the plasmid DNA, wherein said lysing step comprises: moving a suspension of the cells through a first passageway; moving a lysis solution through a second passageway; contacting the suspension of the cells with the lysis solution at an intersection, wherein the intersection is formed by the first and second passageway; and mixing the suspension of the cells and the lysis solution inside a third passageway to form a lysate, wherein the third passageway is downstream from the intersection;

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(b) removing contaminants from the lysate, wherein the removing step comprises: moving the lysate through the third passageway and into a container, wherein the container contains a salt solution', and mixing the lysate in the salt solution to form a precipitate and a supernatant; wherein the precipitate contains the contaminants;

(c) separating the precipitate from the supernatant and (d) recovering the plasmid DNA from the supernatant.

Dependent claims 54, 57, 64 – 66, 68, 74, 75 and 77 are drawn to use of the following in accordance with claim 53, an in line mixer, 100-200 L of volume capacity, flow rate of 1 L/min., use of a non acidic unbuffered salt solution in the form of acetate or chloride, basic lysis solution, precipitate comprising contaminants consisting of RNA, chromosomal DNA, lipids and protein.

Claim 55 is drawn to the use of an impeller mixer, claim 56 is drawn to the use of a jacket around the precipitation reaction tank, claims 57- 60, 63 are drawn to supercoiled DNA and yields of at least 60%, and chilling the initial precipitant.

Claims 67 and 69 are drawn to the concentration of the salt being above 5 M. Claims 70-73 are drawn to the use of a mixture of two salts for the precipitation.

Claim 76 is drawn to the use of sodium hydroxide and a detergent as the lysing solution.

Claims 78-90 are drawn to the use of column chromatography, hydrophobic interaction or anion exchange after isolation of the plasmid DNA.

Claims 91-103 are drawn to a device for carrying out the method cited in claim 53.

Wan teaches a method for lysing cells using a dual line feed of cell suspension and lysing solution to a primary static mixer; wherein the lysate is fed to a secondary static mixer with a precipitating solution fed separately to the secondary static mixer. Wan anticipates the dependent claims as it further teaches a flow rate of 1 L/min. (col.4, line 18), use of a non acidic unbuffered salt solution in the form of acetate or chloride (col.3,

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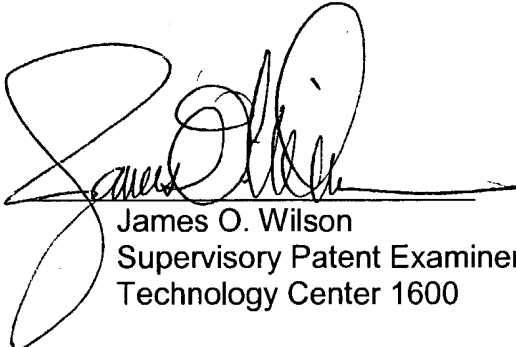
line 50), basic lysis solution (col. 3, lines 19-21), wherein the precipitate comprising contaminants consisting of RNA, chromosomal DNA, lipids and protein, col. 3- col.4).

Wan however does not teach the use of the anion exchange and hydrophobic interaction columns as set forth in claims 104-114 in the purification of plasmid DNA. Kasai bridges the nexus between the prior art and the instant claims as it teaches the use of anion exchange and hydrophobic interaction columns in the separation of nucleic acids.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to use anion exchange chromatography or hydrophobic interaction column chromatography in the purification of plasmid DNA.

A person of ordinary skill in the art would have been motivated to use anion exchange and hydrophobic interaction columns given the established use of these columns in the prior art for the separation and purification of nucleic acids.

Howard V. Owens
Patent Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.